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# Kongeriget Danmark

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Applicant:
(Name and address)

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

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Susanne Morsing

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# INTERNAL NEEDLE INSERTER

The present invention generally relates to the insertion of needles or needle-like members. More specifically, the invention relates to insertion of a needle device at a selected site within the body of a patient for subcutaneous, intravenous, intramuscular or intradermal delivery of a drug to a subject, the needle device being carried by a device comprising a mounting surface adapted for application to the skin of a subject. Especially, the invention relates to insertion of an infusion needle for the infusion of a drug, to insertion of a needle-formed sensor, as well as to insertion of insertion needles for easy placement of a device such as a sensor through the skin of a subject.

## BACKGROUND OF THE INVENTION

In the disclosure of the present invention reference is mostly made to the treatment of diabetes by injection or infusion of insulin, however, this is only an exemplary use of the present invention.

Portable drug delivery devices for delivering a drug to a patient are well known and generally comprise a reservoir adapted to contain a liquid drug and having an outlet in fluid communication with a hollow infusion needle, as well as expelling means for expelling a drug out of the reservoir and through the skin of the subject via the hollow needle. Such devices are often termed infusion pumps.

Basically, infusion pumps can be divided into two classes. The first class comprises durable infusion pumps which are relatively expensive pumps intended for 3-4 years use, for which reason the initial cost for such a pump often is a barrier to this type of therapy. Although more complex than traditional syringes and pens, the pump offer the advantages of continuous infusion of insulin, precision in dosing and optionally programmable delivery profiles and user actuated bolus infusions in connections with meals.

Addressing the above problem, several attempts have been made to provide a second class of drug infusion devices that are low in cost and convenient to use. Some of these devices are intended to be partially or entirely disposable and may provide many of the advantages associated with an infusion pump without the attendant cost and inconveniencies, e.g. the pump may be prefilled thus avoiding the need for filling or refilling a drug reservoir. Exam-

ples of this type of infusion devices are known from US patents 4,340,048 and 4,552,561 (based on osmotic pumps), US patent 5,858,001 (based on a piston pump), US patent 6,280,148 (based on a membrane pump), US patent 5,957,895 (based on a flow restrictor pump (also know as a bleeding hole pump), US patent 5,527,288 (based on a gas generating pump), or US patent 5,814,020 (based on a swellable gel) which all in the last decades have been proposed for use in inexpensive, primarily disposable drug infusion devices, the cited documents being incorporated by reference.

The disposable pumps generally comprises a skin-contacting mounting surface adapted for application to the skin of a subject by adhesive means, and with the infusion needle arranged such that in a situation of use it projects from the mounting surface to thereby penetrate the skin of the subject, whereby the place where the needle penetrates the skin is covered while the appliance is in use.

The infusion needle may be arranged to permanently project from the mounting surface such that the needle is inserted simultaneously with the application of the infusion pump. Examples of this configuration can be found in US patents 2,605,765, 4,340,048 and in EP 1 177 802. Although this configuration provides a simple and cost-effective solution, the actual user-performed piercing of the tissue with the needle is often problematic as people who are not experts in medicine are usually insufficiently practised to place such a needle correctly and they often suffer from a fear of the likely pain. Although not relating specifically to infusion pumps, US patent 5,851,197 discloses an injector in which an infusion set comprising a skin-mountable surface with a protruding needle can be mounted, the injector upon actuation driving the entire infusion set into contact with a skin portion whereby the needle is inserted through the skin.

Addressing the above problem, infusion pump devices have been proposed in which the pump device is supplied to the user with the needle in a retracted state, i.e. with the distal pointed end of the needle "hidden" inside the pump device, this allowing the user to place the pump device on the skin without the possibility of observing the needle. When first the needle is hidden, at least some of the fear is overcome making the introduction of the needle in a second step less problematic. US patents 5,858,001 and 5,814,020 disclose infusion devices of this type in which an infusion needle is arranged in an upper housing portion pivotably arranged relative to a base plate portion. In this way the user can introduce the needle by pressing the upper portion into engagement with the base plate portion.

To further reduce the fear and pain associated with the introduction of the needle, many recent pump devices have been provided with actuatable needle insertion means, which just has to be released by the user after which e.g. spring means quickly will advance the needle through the skin.

For example, US patent 5,957,895 discloses a liquid drug delivery device comprising a bent injection needle which is adapted to project through a needle aperture in the bottom surface of the housing in a situation of use. A movable needle carrier is disposed in the housing for carrying the injection needle and for causing the injection end of the needle to project through the needle aperture upon movement of the needle carrier.

US patent 5,931,814 discloses an infusion device having a housing with a drug reservoir, an infusion needle (or cannula) communicating with the reservoir, means for inserting the needle, and pump means for discharging the reservoir contents through the needle. The needle is fixed relative to the housing and projects beyond the lower skin-contacting surface of the housing to the depth required for injection. The needle is surrounded by a protective element which is moved by spring means from a first end position in which the protective device projects beyond the lower surface of the housing and beyond the needle to a second end position in which the protective device does not project beyond the underside of the casing. An advantage of this design is that the needle is arranged in a fixed position relative to the reservoir. WO 02/15965 discloses a similar infusion device in which a base plate member acts as a protecting element until an upper part of the device, to which the needle is fixed, is moved down into engagement with the base plate member.

In the devices disclosed in US patents 5,957,895 and 5,931,814 the needle is automatically inserted by the release of pre-tensioned spring means arranged within the devices, whereas in the device known from WO 02/15965 the needle is inserted by the user actively moving the hidden needle. Although the automatic needle insertion means adds convenience for the user and may serve to overcome needle fear, such means also adds to the complexity and thus to the cost of the device, just as they may reduce the reliability.

Before turning to the disclosure of the present invention, a different type of device relying on the insertion of a needle or needle-like structure will be described.

Although drug infusion pumps, either disposable or durable, may provide convenience of use and improved treatment control, it has long been an object to provide a drug infusion system for the treatment of e.g. diabetes which would rely on closed loop control, i.e. being more or less fully automatic, such a system being based on the measurement of a value indicative of the condition treated, e.g. the blood glucose level in case of insulin treatment of diabetes.

A given monitor system for measuring the concentration of a given substance may be based on invasive or non-invasive measuring principles. An example of the latter would be a non-invasive glucose monitor arranged on the skin surface of a patient and using near-IR spectroscopy, however, the present invention is concerned with the introduction of a transcutaneous device such as a needle-formed sensor element.

The sensor may be placed subcutaneously being connected to external equipment by wiring or the substance (e.g. fluid) to be analysed may be transported to an external sensor element, both arrangements requiring the placement of a subcutaneous component (e.g. small catheter or tubing), the present invention addressing both arrangements. However, for simplicity the term "sensor" is used in the following for both types of elements introduced into the subject.

Turning to the sensor elements *per se*, relatively small and flexible electrochemical sensors have been developed for subcutaneous placement of sensor electrodes in direct contact with patient blood or other extra-cellular fluid (see for example US patent 5,482,473), wherein such sensors can be used to obtain periodic or continuous readings over a period of time. Insertion devices for this type of sensors are described in, among others, US patents 5,390,671, 5,391,950, 5,568,806 and 5,954,643 which hereby are incorporated by reference.

More specifically, US patent 5,954,643 discloses an insertion set comprising a mounting base supporting a proximal end of a flexible thin film sensor, the sensor including a distal segment with sensor electrodes thereon which protrudes from the mounting base for transcutaneous placement, wherein the sensor distal segment is slidably carried by a slotted insertion needle fitted through the assembled base. Placement of the insertion set against the patient's skin causes the insertion needle to pierce the skin to carry the sensor electrodes to the desired subcutaneous site, after which the insertion needle can be slidably withdrawn from the insertion set. A similar arrangement is known from US patent 5,568,806.

## DISCLOSURE OF THE INVENTION

Having regard to the above-identified problems, it is an object of the present invention to provide a needle-carrying device comprising needle insertion means (or driving means) which allows for easy and swift, automatic needle insertion, yet is reliable in use. The device should be compact in size and be designed for cost effective manufacturing.

The present invention provides that the needle insertion means can be activated by the user during actuation of the needle insertion means. In this context the term "activation" of the needle insertion means relates to the energizing thereof, whereas the term "actuation" relates to the user-related input responsible for both energizing and release of the needle insertion means.

Correspondingly, a medical device is provided, comprising a housing having a mounting surface adapted for application to the skin of a subject, a needle unit comprising a needle with a distal, pointed end portion adapted to penetrate the skin of the subject, wherein the needle has a first position in which the distal end portion is retracted within the housing, and a second position in which the distal end portion projects relative to the mounting surface. The device further comprises actuatable driving means disposed within the housing and adapted to move the needle from the first position to the second position when the driving means is actuated, wherein the driving means is actuatable from a first state through an intermediate state to a second state, whereby actuation of the driving means from the first to the intermediate state causes activation of the driving means, and actuation of the driving means from the intermediate to the second state causes release of the activated driving means thereby moving the needle from the first position to the second position. As the device normally will be supplied to the user with the needle in the first position, the first state may also be termed an initial state just as the second state may be termed an active state.

It should be emphasized that the activated state not necessarily is a stable state in which the spring means can be left, but a state which may require that an actuation input (e.g. a force applied by the user) is upheld, i.e. the spring means may resume an initial state if the actuation input is removed. Further, the actuation means may be partly energized in their initial state.

By this arrangement a needle device is provided which can be supplied to the user in a non-energized state, the energizing taking place when the device is actuated by the user which means that energy will be stored only for a period from a few seconds to a few hours or days. For example, the device may be designed such that the drive means is fully depleted from energy when the needle has been inserted (e.g. by locking the needle in its second position), or it may be designed to exert a biasing force upon the needle in its second position. In this way the drive means and the elements upon which a force is exerted by the drive means can be optimized for a very short "active" life, this in contrast to arrangements in which energy is stored corresponding to the entire shelf life of the device, e.g. one or more years. For example, much higher requirements would have to be fulfilled for a polymer spring adapted for storing energy during a period of several years, or by a polymer structure adapted for locking a metal spring during a corresponding period. Further, to prevent structures from locking (e.g. "growing together") during storage, it may be necessary to store additional energy to overcome a possible locking resistance, this adding to the aforementioned problems. Further again, by providing a device which can be shipped, stored and handled in a non-energized condition, the risk of accidental actuation will be reduced.

In exemplary embodiments the driving means comprises spring means adapted for releasably storing energy which can be activated respectively released when the driving means is actuated from the first state through the intermediate state to the second state by the user. The spring means may comprise any elastically compressible or deformable means, e.g. a metal or polymer member, an elastomeric foam or a gas. The driving means may be arranged to exert a force on the needle unit in the second state thereby biasing the needle distal end portion towards the second position. In exemplary embodiments the mounting surface comprises a needle aperture formed therein, the distal end portion of the needle being moved through the aperture when the needle is moved from the first to the second position. Advantageously, the spring means comprises a drive portion adapted to engage an engagement portion of the needle unit when the spring means is released (e.g. the two portions actually coming into engagement with each other), wherein activation of the spring means causes an activation movement of the drive portion corresponding to the movement by which energy is releasably stored in the spring means, and a displacement movement, different from the activation movement, in which the drive portion and the engagement portion are moved relative to each other. In other words, when the user activates the spring means two actions take place: The spring is compressed and positioned relative to the portion of the needle unit which it is adapted to engage when released. The positioning may take place by

moving the spring means, the needle unit or both. Advantageously the spring means will directly engage the needle or the structure carrying the needle, however, the needle unit may be provided with transfer or linkage means allowing the spring means to act indirectly on the needle, e.g. when it is desirable to transform a primary movement of the spring means such as from an upwards to a downwards movement.

The needle may be introduced subcutaneously at any desired angel relative to the mounting surface (and thus the skin surface), e.g. in the second position the distal end portion may extend generally perpendicular to the mounting surface.

To provide a compact device, the drive portion corresponding to the first state may be arranged below and beside the engagement portion (with respect to the mounting surface), and such that the drive portion corresponding to the intermediate state is arranged in an upper position substantially above the engagement portion. By this arrangement release of the spring means causes downwards movement of the drive portion to engage the engagement portion whereby the needle is moved from the first position to the second position.

To allow the user to activate and release the drive means, the device advantageously comprises actuation means moveable from a first position through an intermediate position to a second position, whereby movement of the actuation means from the first to the intermediate position causes activation of the spring means, and movement from the intermediate to the second position causes release of the activated spring means thereby moving the needle from the first position to the second position. The actuation means may be in the form of user actuatable element which can be gripped or moved by the user relative to the housing (e.g. a button), or a (major) portion of the housing may be moveable relative to a base portion comprising the mounting surface. The movement preferably corresponds to a substantially non-composite movement (e.g. a unidirectional linear or rotational movement which may be with or without an intermediate lockable state). In an alternative arrangement actuation of the actuation means from the first through the intermediate to the second condition is accomplished by moving two actuation elements against each.

In an exemplary embodiment the spring means is coupled to the actuation means, whereby the displacement movement of the drive portion substantially corresponds to the movement of the actuation means from the first to the intermediate position.

Advantageously, the device comprises ramp (or lifting) means adapted to engage the spring means, such that movement of the actuation means from the first to the intermediate position causes the ramp means to move (lift) the drive portion to its upper position, and movement of the actuation means from the intermediate position to the second position causes the ramp means to disengage and thereby release the spring means. The spring means may comprise a spring member (e.g. a "physical" member such as a leaf spring or a "piano" string, this in contrast to a gas spring) having a proximal end mounted to the actuation means and a distal deflectable end portion comprising the drive portion, the distal end portion engaging the ramp means.

In an exemplary embodiment, the needle unit comprises a needle carrier carrying the needle, the needle carrier being coupled (e.g. pivotally) to the housing for controlled movement of the needle between the first and second positions.

As indicated above, the present invention may be utilized in combination with a number of different types of devices.

For example, for a medical device as described above the needle may be in the form of a hollow infusion needle, the first unit further comprising a reservoir adapted to contain a liquid drug and comprising in a situation of use an outlet in fluid communication with the infusion needle, as well as expelling means for expelling a drug out of the reservoir and through the skin of the subject via the hollow needle. The reservoir and the expelling means may be of any suitable type, e.g. of any of the types described in the above-referred documents. The reservoir may be connected to the actuation means, and arranged such that movement of the actuation means between the first and the second position causes the reservoir to be arranged in fluid communication with the infusion needle. Advantageously, movement of the actuation means between the first and the second position causes actuation of the expelling means.

The needle may also be in the form of a needle sensor comprising sensor means capable of being influenced by a body substance and producing a signal corresponding thereto. The sensor means may be of any suitable type, e.g. of any of the types described in the above-referred documents.

In a further embodiment the first unit comprises an additional needle-formed member having a distal end, the needle-formed member having a first retracted position relative to the second unit, and a second position in which the distal end projects relative to the second unit, wherein the needle is in the form of a removable insertion needle arranged co-axially with and supporting the needle-formed member, the insertion needle and the needle-formed member being arranged to be simultaneously moved by the driving means from their respective first position to their respective second position when the driving means is actuated. Corresponding to the first and second specific aspects the insertion needle may be fixed or moveable relative to the mounting surface. The insertion needle may have any desirable configuration such as solid or grooved.

For any of the above-described embodiments, the mounting surface advantageously comprises adhesive means for adhering the first unit to the skin of the subject.

As used herein, the term "drug" is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension. Representative drugs include pharmaceuticals such as peptides, proteins, and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form. Correspondingly, the term "subcutaneous infusion" is meant to encompass any method in which a needle device is inserted at a selected site within the body of a patient for subcutaneous, intravenous, intramuscular or intradermal delivery of a drug to a subject. Further, the term needle or needle device (when not otherwise specified) defines a piercing member (including an array of micro needles) adapted to be introduced into or through the skin of a subject.

## BRIEF DESCRIPTION OF THE DRAWINGS

In the following the invention will be further described with references to the drawings, wherein

fig. 1A shows in a perspective view a first embodiment of a medical device gripped by a user corresponding to a first state of use,

fig. 1B shows the device of fig. 1A with a portion of the housing cut off,

fig. 1C shows the device of fig. 1A with a portion of the housing removed,

fig. 1D shows the device of fig. 1A seen from a different angle with a portion of the housing cut off,

fig. 1E shows the device of fig. 1D with a portion of the housing removed,

figs. 2A-2E shows an intermediate state of use corresponding to figs. 1A-1E,

figs. 3A-3E shows a second state of use corresponding to figs. 1A-1E,

fig. 4A shows in a perspective view a second embodiment of a medical device gripped by a user corresponding to a first state of use,

fig. 4B shows the device of fig. 4A with a portion of the housing cut off,

fig. 4C shows the device of fig. 4A with a portion of the housing removed,

fig. 4D shows the device of fig. 4A seen from a different angle with a portion of the housing cut off,

fig. 4E shows the device of fig. 4D with a portion of the housing removed,

figs. 5A-5E shows an intermediate state of use corresponding to figs. 4A-4E,

figs. 6A-6E shows a second state of use corresponding to figs. 4A-4E,

fig. 7 shows a needle carrier, and

figs. 8A-8D shows different expelling means suitable for use with the invention.

In the figures like structures are identified by like reference numerals.

## DESCRIPTION OF EXEMPLARY EMBODIMENTS

When in the following terms as "upper" and "lower", "right" and "left", "horizontal" and "vertical" or similar relative expressions are used, these only refer to the appended figures and not to an actual situation of use.

Figs. 1-3 show in schematic representations perspective views of different states of use of a medical device in accordance with the invention. Correspondingly, the configuration of the different structures as well as there relative dimensions are intended to serve illustrative purposes only.

More specifically, fig. 1A shows a first embodiment of a medical device 100 gripped by a user. The medical device comprises a housing with an upper housing portion 110 and a lower base plate portion 120, the housing providing a cavity in which an actuation member 130 is slidingly received through an opening, the actuation element being moveable corresponding to a longitudinal direction in respect of the device. The base plate portion comprises an adhesive mounting surface 121 adapted for application to the skin of a subject, the mounting surface being generally planar and defining a general plane. The actuation member comprises a ribbed area allowing for easy gripping by a user, e.g. using the first and second fingers as shown.

In the shown embodiment the actuation member is formed as a frame having opposed side portions 131, 132 adapted to be in sliding engagement with inner surface portions of the upper housing portions, the inner surface portions comprising longitudinally ridges received in corresponding grooves formed on the outer surfaces of the side portions. The two side portions are connected by a button portion 135 corresponding to an outer end and by a bridge portion 136 corresponding to an inner end thereof, the bridge portion comprising a spring means in the form of a leaf spring 137 having a free end portion with an inclined orientation relative to the base plate portion, the leaf spring serving as an insertion spring. The leaf spring may be attached to the bridge portion (e.g. when made from a metal alloy) or it may be formed integrally with the actuation member (e.g. manufactured from a polymer). The base plate portion comprises an upper surface on which a female hinge member 138 and a ramp member 139 are formed, preferably formed integrally with the base plate portion. The ramp member comprises an upper inclined ramp surface 147 adapted to engage a lower surface of the leaf spring 137 (serving as a drive portion adapted to engage a corresponding engagement portion on the needle unit), the ramp surface terminating in an upper free edge

148. Although not literally a ramp, the term "ramp" also covers the embodiment in which a narrow upstanding wall terminates in a free edge over which the leaf spring slides.

The device further comprises a needle unit 150 connected to the base plate portion by a hinge allowing the needle unit to pivot corresponding to a pivoting axis defined by the hinge, the pivoting axis being arranged substantially in parallel with the mounting surface. The needle unit comprises a hollow infusion needle (see fig. 7) having a distal pointed outlet portion 151 adapted to penetrate the skin of the subject, the outlet portion extending generally perpendicular to the mounting surface, and a pointed proximal inlet portion 152 arranged substantially corresponding to the pivoting axis. The distal end may be straight or curved, e.g. arcuate corresponding to the pivoting axis. The needle is carried by a needle carrier comprising an arm portion 153 and a cylindrical male hinge portion, the needle carrier being connected to the female hinge member thereby forming the hinge. The arm comprises a biasing member in the form of a leaf spring 155 projecting therefrom, the spring being in engagement with the upper surface of the base plate member thereby providing an upwardly directed biasing force forcing the needle into its initial position.

By this arrangement the needle unit can pivot between an initial position in which the inlet portion of the needle is retracted within the housing, and a second position in which the inlet portion projects relative to the mounting surface through an opening (not to be seen in the figs.) formed in the base plate portion. In the disclosed embodiments the hinge is provided by cooperating members of the needle carrier respectively the housing, however, a "naked" needle may be connected to the housing or the needle carrier and the housing may be formed integrally connected to each other by a film-hinge.

The device further comprises a reservoir 160 adapted to contain a liquid drug and comprising in a situation of use an outlet in fluid communication with the infusion needle, and expelling means (not shown for better illustrating the principles of the invention) for expelling a drug out of the reservoir and through the skin of the subject via the hollow needle. The reservoir and the expelling means are mounted on the actuation member and thus moveable relative to the housing. The reservoir comprises a needle-penetratable septum 161 adapted to cooperate with the inlet portion of the infusion needle, the septum being arranged substantially corresponding to the pivoting axis, thereby allowing the needle unit to pivot substantially without non-rotational displacement of the inlet portion of the infusion needle relative to the septum.

With reference to figs. 2 and 3 use and actuation of the device 100 will be described.

After having placed the medical device on a skin portion, the user presses the actuation member 130 into the housing whereby the needle is inserted and the delivery means started. During this action the actuation member is moved from a first (initial) position through an intermediate position to a second position. During movement of the actuation member from the first to the intermediate position the insertion spring 137 is moved relative to the ramp member, this causing an upwards activation movement of the drive portion whereby energy is releasably stored in the spring, and a displacement movement in which the drive portion is moved to a position above the engagement portion of the needle unit. At the same time the reservoir is moved into fluid communication with the infusion needle. After this, actuation of the actuation member from the intermediate to the second position causes release of the activated spring (when the distal free edge of the insertion spring slides over the upper free edge of the ramp, whereby the insertion spring in a snap-action engages the needle unit thereby biasing it downwardly to its second position against the force of the biasing spring 155. At the same time the actuation member is locked in place by the insertion spring being locked behind the ramp member.

The delivery means or sensor electronics will have to be actuated in combination with insertion of the needle, either in combination with the above-described actuation of the needle (e.g. by closing an electric contact or by providing a fluid communication) or by using additional actuation means which may be operated separately after the device has been mounted on the skin and the needle introduced.

In figs. 4-6 is shown a second embodiment of a medical device 200 similar to the first embodiment, the device comprising an upper housing portion 210 and a lower base plate portion 220, the housing providing a cavity in which an actuation member 230 is slidingly received through an opening, the actuation element being moveable corresponding to a longitudinal direction. The device further comprises a reservoir 260 and a needle unit 250. The device also comprises an inserter spring 237 and a ramp member 247, however, in contrast to the first embodiment the inserter spring is in the form of a thin rod (or string) just as the ramp member is arranged to deflect the inserter spring upwards as well as sidewards.

More specifically, the ramp surface is somewhat longer and has a concave cross-sectional configuration, this allowing the rod spring to slide thereon without accidental disengagement. The ramp terminates in an obliquely oriented deflection wall 249 which will force the spring rod outwards when forced thereagainst. The rod may be formed integrally with the actuation member or attached as a separate member, e.g. as a metal string. The needle unit is similar to the first embodiment apart from comprising a separately formed engagement portion 257 projecting from the distal end of the carrier arm and arranged on the side of the ramp member just below the deflection wall. Further, in contrast to the first embodiment, the actuation member does not comprise a bridge portion connecting the inner ends of the side portions.

In use, the second embodiment is actuated in the same way as the first embodiment, the primary difference being that the insertion spring is released from the upper ramp surface by a sidewards movement provided by the deflection wall.

In the above described embodiments, the actuation member has been moved linearly, however, it may other movements may be utilized in accordance with the invention. For example, a medical device may have a circular configuration in which actuation may be provided by the user rotating an upper portion of the housing. In such an arrangement the insertion spring may extend radially with a free peripheral end sliding on a curved ramp.

In the above described embodiments, the needle has been in the form of a unitary needle device (e.g. an infusion needle as shown or a needle sensor (not shown), however, a needle device may also be introduced subcutaneously in combination with an insertion needle which is withdrawn after insertion thereof.

Fig. 7 shows a needle unit 150 adapted to be connected to a housing member by a hinge allowing the needle unit to pivot corresponding to a pivoting axis defined by the hinge. More specifically, the needle unit comprises a needle carrier having a cylindrical hinge portion 154 defining the pivoting axis, and an arm member 153 extending perpendicularly from the hinge portion in respect of the pivoting axis. On a lower surface of the arm member a biasing means is arranged in the form of a leaf spring member 155 adapted to engage a portion of the housing. The needle carrier carries a needle having a distal pointed portion 151 adapted to penetrate the skin of the subject, the distal portion extending generally perpendicular to the mounting surface, and a proximal portion (152) arranged substantially corresponding to the pivoting axis. In this way the needle unit can be arranged to pivot between a first position

in which the distal portion of the needle is retracted within a housing, and a second position in which the inlet portion projects relative to a mounting surface.

In the above-described embodiments a medical device has been described comprising a reservoir, however, for better illustrating the principles of the present invention, the means for expelling a drug from the reservoir has been omitted in the figures. Such expelling means, which as the reservoir does not form part of the present invention in its basic form, may be of any type which would be suitable for arrangement within a skin-mountable drug delivery device. Further, as the needle of the present invention also may be in the form of a needle sensor, the interior of the medical device may comprise sensor means adapted to cooperate with the needle sensor.

In figs. 8A-8D examples of expelling means suitable for use with the present invention are shown schematically, however, these are merely examples. More specifically, fig. 8A shows a pump arrangement comprising a drug-containing cartridge 1010 having a distal closure member 1011 allowing a needle to be connected, and a piston 1015 slidingly arranged there within, a flexible toothed piston rod 1020 (for example as disclosed in US patent 6,302,869), an electric motor 1030 which via a worm-gear arrangement 1031 drives the piston rod to expel drug from the cartridge, the motor being controlled by control means 1040 and the energy for the control means and the motor being provided by a battery 1050. The pump may be activated when the needle is inserted (by means not shown) or by separate user-actuatable means (not shown) after the inserter has been detached form the delivery device.

Fig. 8B shows a pump arrangement comprising a drug-containing cartridge 1110 having distal and proximal closure members 1111, 1112, and a piston 1115 slidingly arranged there within, gas generating means 1120 in fluid communication with the interior of the cartridge via conduit 1121 for driving the piston to expel drug from the cartridge, the gas generating means being controlled by control means 1140 and the energy for the control means and the gas generation being provided by a battery 1150. The pump may be activated as indicated above. A detailed disclosure of such gas generating means for a drug delivery device can be found in e.g. US patent 5,858,001.

Fig. 8C shows a pump arrangement comprising a drug-containing cartridge 1210 having distal and proximal closure members 1211, 1212, and a piston slidingly 1215 arranged there within, an osmotic engine 1220 in fluid communication with the interior of the cartridge via

conduit 1221 for driving the piston to expel drug from the cartridge. The osmotic engine comprises a first rigid reservoir 1225 containing a salt-solution and a second collapsible reservoir 1226 containing water, the two reservoirs being separated by a semi-permeable membrane 1227. When supplied to the user, the fluid connection 1228 between the second reservoir and the membrane is closed by a user-severable membrane (e.g. a weak weld) which, when severed, will allow the osmotic process to start as water is drawn from the second reservoir through the membrane and into the first reservoir. The pump may be activated as indicated above. A detailed disclosure of the osmotic drive principle can be found in e.g. US patent 5,169,390.

Fig. 8D shows a pump arrangement comprising a drug-containing flexible reservoir 1310 arranged within a rigid fluid-filled secondary reservoir 1311 in fluid communication with a primary reservoir 1320 through a conduit 1330 comprising a flow restrictor 1331. The primary reservoir is in the form of a cartridge with a moveable piston 1321 and contains a viscous drive fluid. A spring is arranged to act on the piston to drive fluid from the first to the second reservoir thereby expelling drug from the flexible reservoir when the latter is connected to an infusion needle (not shown). The flow rate will be determined by the pressure generated by the spring in the drive fluid, the viscosity of the drive fluid and the flow resistance in the flow restrictor (i.e. bleeding hole principle). The pump may be activated by straining the spring or by releasing a pre-stressed spring, either when the needle is inserted (by means not shown) or by separate user-actuatable means (not shown) after the inserter has been detached form the delivery device. An example of this principle used for drug infusion is known from DE 25 52 446. In an alternative configuration, the drug reservoir may be pressurized directly to expel the drug via a flow restrictor, e.g. as disclosed in US patent 6,074,369.

In the above description of the preferred embodiments, the different structures and means providing the described functionality for the different components have been described to a degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

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## CLAIMS

1. A medical device (100) comprising:

- a housing (110, 120) having a mounting surface (121) adapted for application to the skin of a subject,
- a needle unit (150) comprising a needle with a distal pointed end portion (151) adapted to penetrate the skin of the subject,
- the needle having a first position in which the distal end portion is retracted within the housing, and a second position in which the distal end portion projects relative to the mounting surface,
- actuatable driving means (137) disposed within the housing and adapted to move the needle from the first position to the second position when the driving means is actuated,
- wherein the driving means is actuatable from a first state through an intermediate state to a second state,
- whereby actuation of the driving means from the first to the intermediate state causes activation of the driving means, and actuation of the driving means from the intermediate to the second state causes release of the activated driving means thereby moving the needle from the first position to the second position.

2. A medical device as defined in claim 1, wherein the driving means comprises spring means (137) adapted for releasably storing energy and which is activated respectively released when the driving means is actuated from the first state through the intermediate state to the second state.

3. A medical device as defined in claim 2,

- wherein the needle unit comprises an engagement portion,
- wherein the spring means comprises a drive portion adapted to engage the engagement portion when the spring means is released, and
- wherein activation of the spring means causes an activation movement of the drive portion corresponding to the movement by which energy is releasably stored in the spring means, and a displacement movement, different from the activation movement, in which the drive portion and the engagement portion are moved relative to each other.

4. A medical device as defined in claim 3, wherein the drive portion corresponding to the first state, and with respect to the mounting surface, is arranged below and beside the

engagement portion, and wherein the drive portion corresponding to the intermediate state is arranged in an upper position substantially above the engagement portion, release of the spring means causing downwards movement of the drive portion to engage the engagement portion and thereby move the needle from the first position to the second position.

5. A medical device as defined in claim 3 or 4, further comprising actuation means (130) moveable, relative to the housing, from a first position through an intermediate position to a second position,

- whereby movement of the actuation means from the first to the intermediate position causes activation of the spring means, and movement of the actuation means from the intermediate to the second position causes release of the activated spring means thereby moving the needle from the first position to the second position.

6. A medical device as defined in claim 5, wherein the spring means is coupled to the actuation means, the displacement movement of the drive portion substantially corresponding to the movement of the actuation means from the first to the intermediate position.

7. A medical device as defined in claim 6, further comprising ramp means (147) adapted to engage the spring means, whereby movement of the actuation means from the first to the intermediate position causes the ramp means to move the drive portion to its upper position, and movement of the actuation means from the intermediate position to the second position causes the ramp means to disengage and thereby release the spring means.

8. A medical device as defined in claim 7, wherein the spring means comprises a spring member (137) having a proximal end mounted to the actuation means and a distal deflectable end portion comprising the drive portion, the distal end portion engaging the ramp means.

9. A medical device as defined in claim 7, wherein the spring member is in the form of a leaf spring (137) or a string (237).

10. A medical device as defined in any of the previous claims, wherein the needle unit comprises a needle carrier (153, 154) carrying the needle, the needle carrier being coupled to the housing for controlled movement of the needle between the first and second positions.

11. A medical device as defined in claim 10, wherein the needle carrier is pivotally connected to the housing.

12. A medical device as defined in any of the previous claims, wherein the needle is a hollow infusion needle comprising a proximal end and the distal pointed end portion.

13. A medical device as defined in claim 12, further comprising:

- a reservoir (160) adapted to contain a liquid drug and comprising in a situation of use an outlet (161) in fluid communication with the infusion needle, and
- expelling means for expelling a drug out of the reservoir and through the skin of the subject via the hollow needle.

14. A medical device as defined in claim 13 when dependent upon claim 5, wherein the reservoir is connected to the actuation means, whereby movement of the actuation means between the first and the second position causes the reservoir to be arranged in fluid communication with the infusion needle.

15. A medical device as defined in claim 13 or 14, wherein movement of the actuation means between the first and the second position causes actuation of the expelling means.

16. A medical device as defined in any of the claims 5-15, wherein the actuation means is moveable substantially in parallel with the mounting surface.

17. A medical device as defined in any of the previous claims, wherein the driving means in the second state exerts a force on the needle unit thereby biasing the needle distal end portion towards the second position.

18. A medical device as defined in any of the previous claims, wherein the distal end portion extends generally perpendicular to the mounting surface.

19. A medical device as defined in any of the previous claims, wherein the mounting surface comprises a needle aperture formed therein, the distal end portion of the needle being moved through the aperture when the needle is moved from the first to the second position.

20. A medical device as defined in any of the previous claims, wherein the mounting surface comprises adhesive means for adhering the first unit to the skin of the subject.

**ABSTRACT**

A device comprises a housing having a mounting surface adapted for application to the skin of a subject, a needle with a pointed end portion adapted to penetrate the skin the subject, the needle having a first position in which the distal end portion is retracted within the housing, and a second position in which the distal end portion projects relative to the mounting surface. The device further comprises actuatable driving means actuatable to cause activation as well as release of the driving means, thereby moving the needle from the first position to the second position. By this arrangement the needle device can be supplied to the user in a non-energized state, the energizing taking place when the device is actuated by the user which means that energy will be stored only for a period from a few seconds to a few hours or days.

Fig. 1A

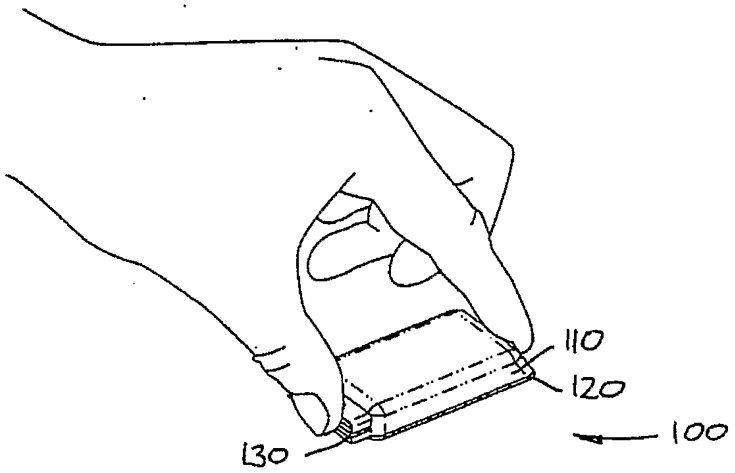



Fig. 1D

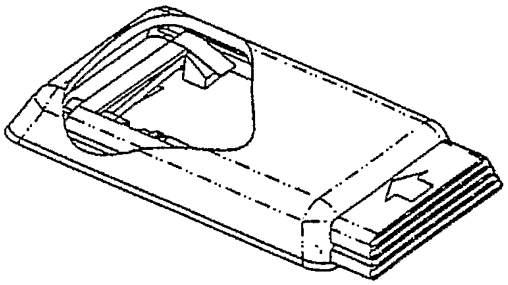


Fig. 1B

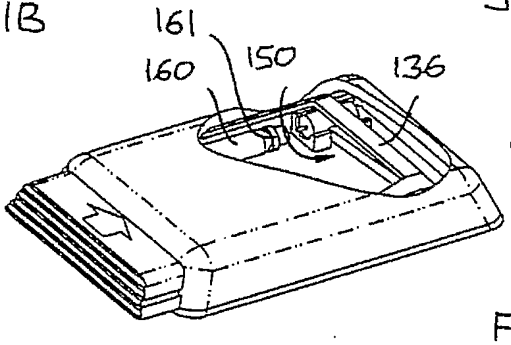



Fig. 1E

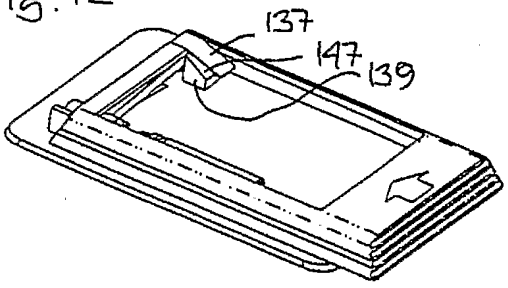



Fig. 1C

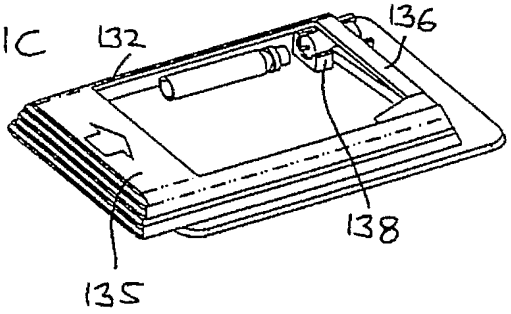


Fig. 2A

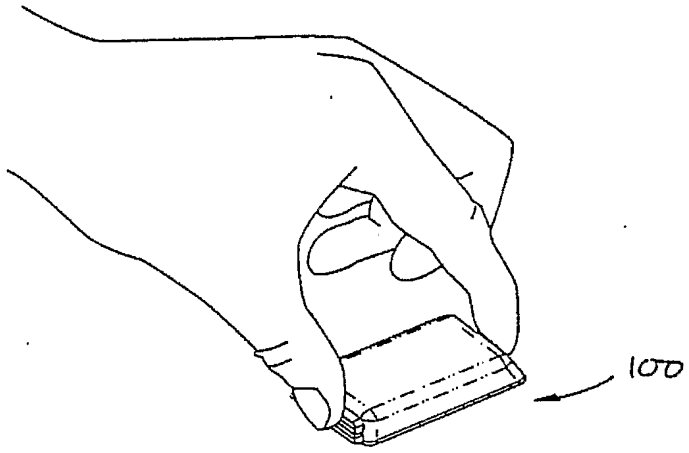



Fig. 2D

Fig. 2B

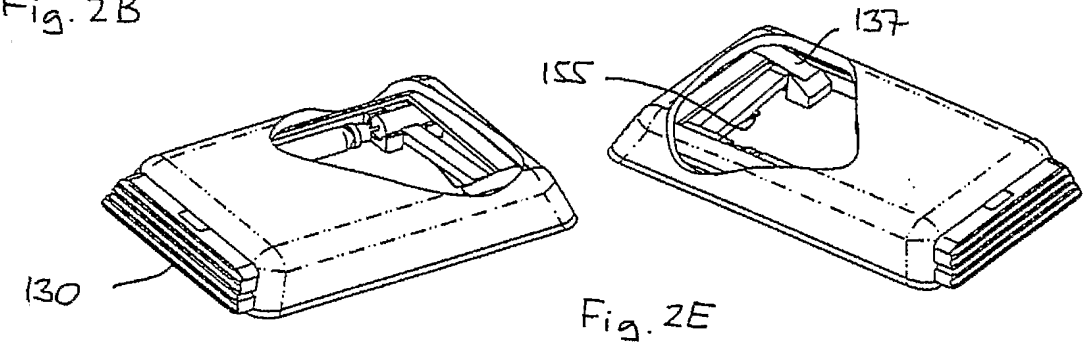



Fig. 2E

Fig. 2C

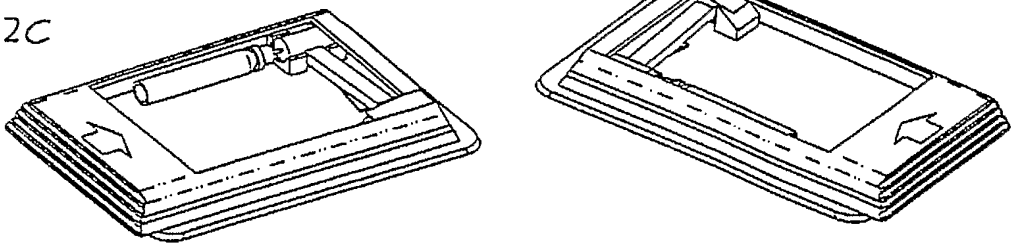


Fig. 3A

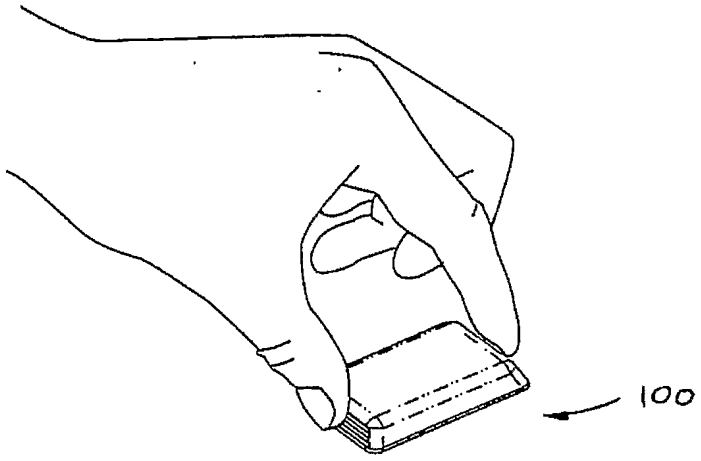



Fig. 3B

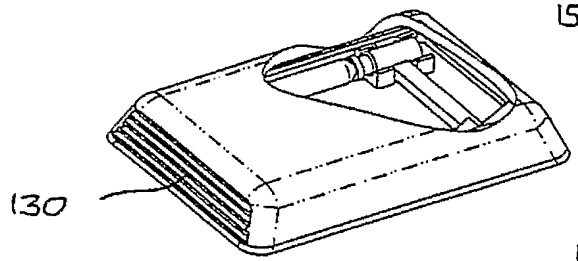



Fig. 3C

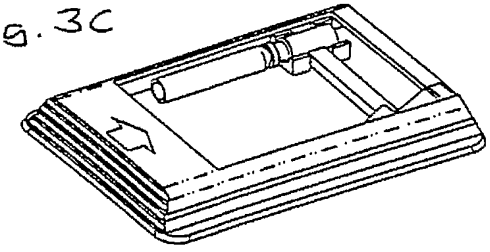


Fig. 3D

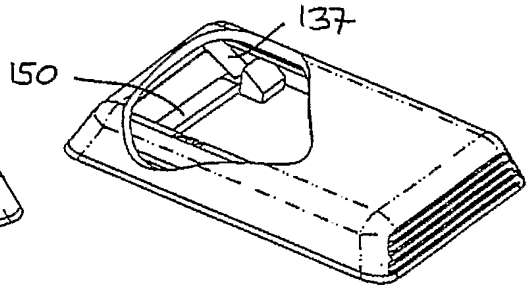



Fig. 3E

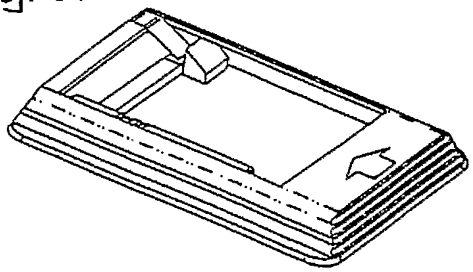


Fig. 4A

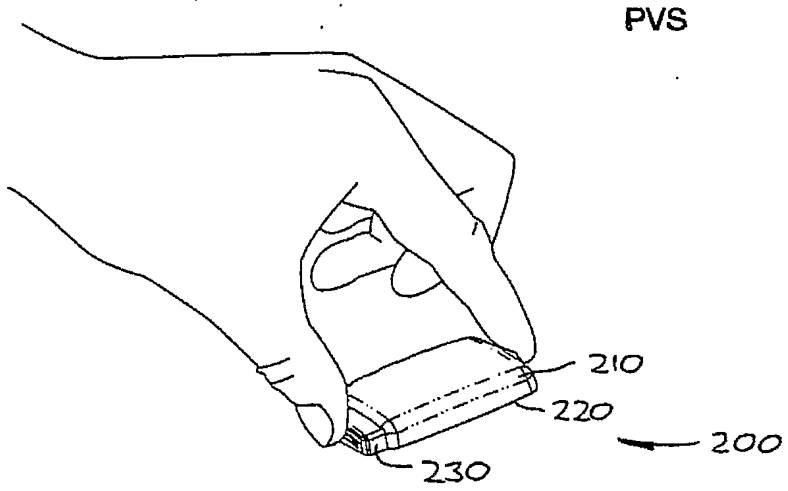



Fig. 4B

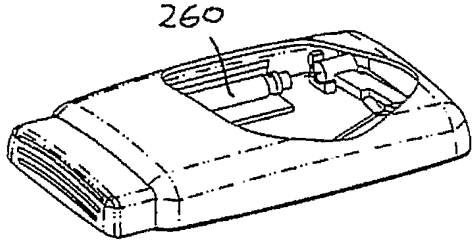
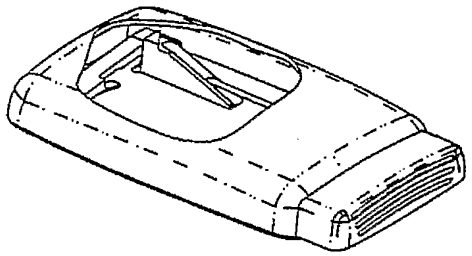



Fig. 4D



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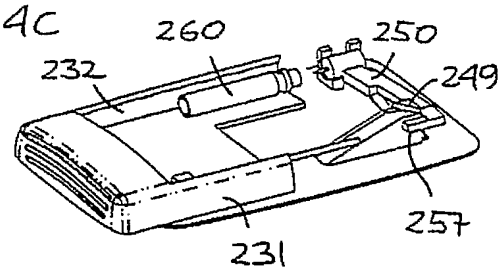


Fig. 4E

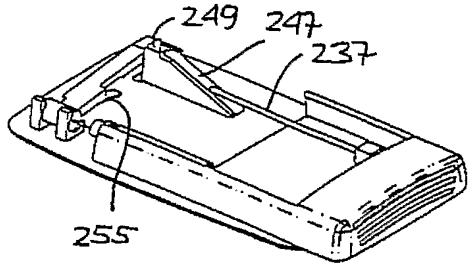

Fig. 5A

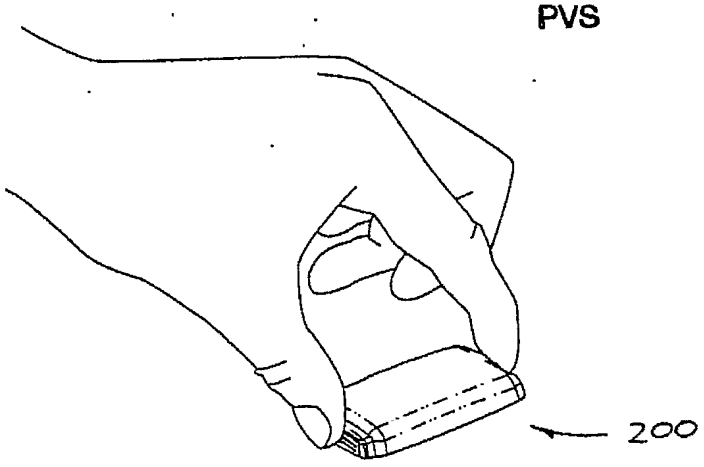


Fig. 5B

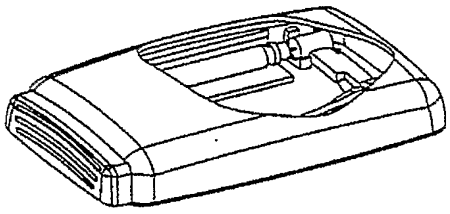

Fig. 5D

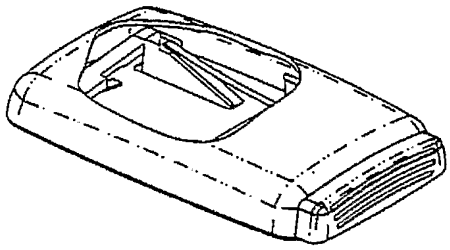

Fig. 5C

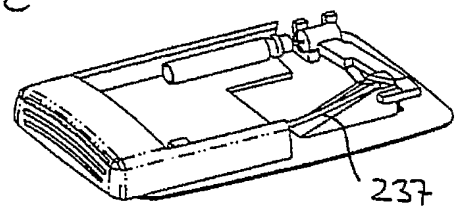


Fig. 5E

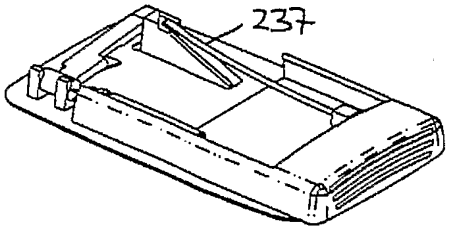

Fig. 6A



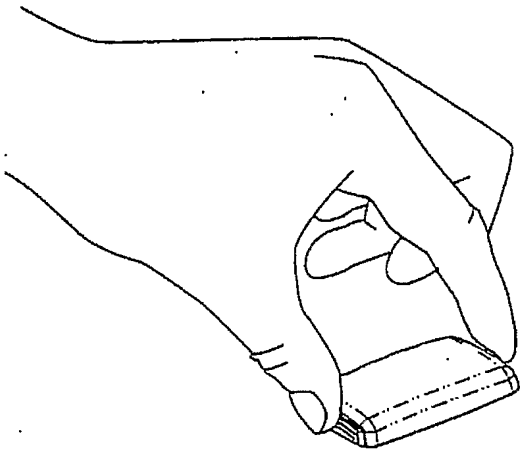


Fig. 6B

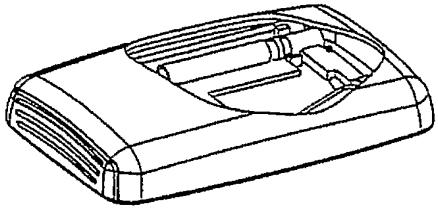

Fig. 6D

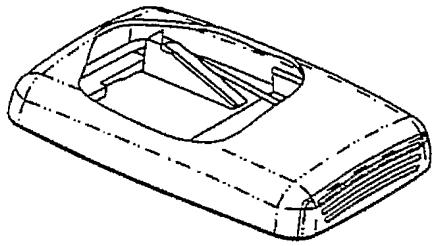

Fig. 6C

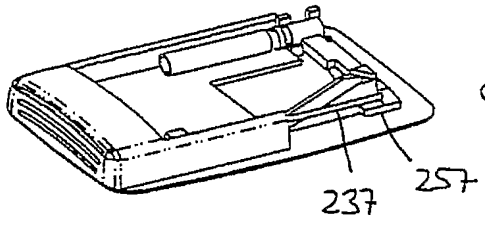


Fig. 6E

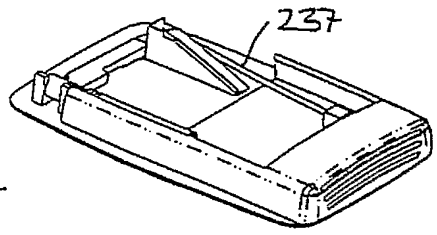

Fig. 7

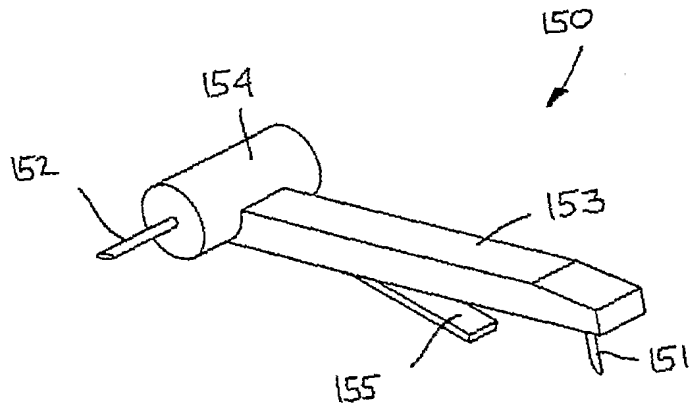

Fig. 8A

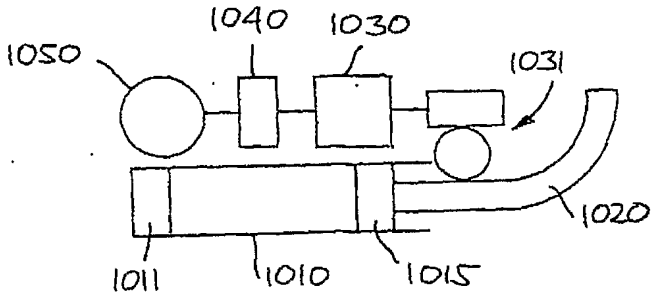


Fig. 8B

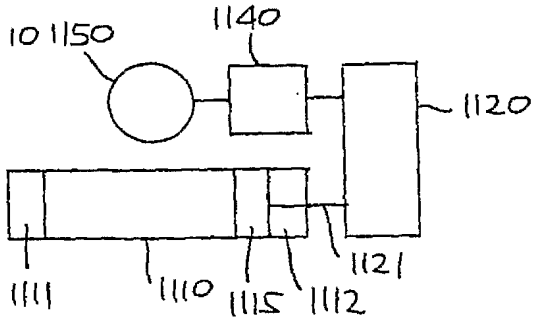


Fig. 8C

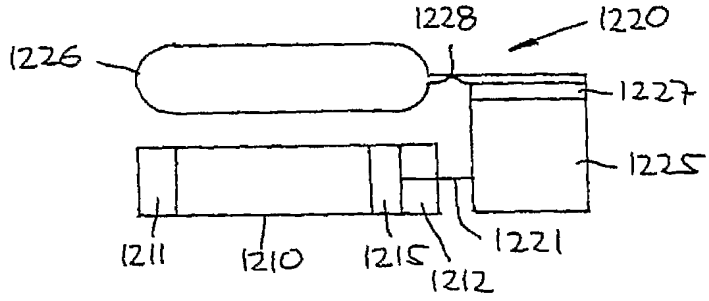


Fig. 8D